

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

In re: BAIR HUGGER FORCED AIR  
WARMING DEVICES PRODUCTS  
LIABILITY LITIGATION

MDL No. 15-2666 (JNE/DTS)

ORDER

This Document Relates to All Cases

This matter is before the Court on Defendants’ Motion for Reconsideration of the Court’s December 13, 2017 Order on General Causation. On January 24, 2019, Defendants filed their Motion for Reconsideration. MDL ECF No. 1718. On February 21, 2019, Plaintiffs filed their Memorandum in Opposition. MDL ECF No. 1786. Defendants replied on March 14, 2019. MDL ECF No. 1849.

The Court requests that the parties address the following issues:

1. Differential diagnosis or etiology is a well-recognized “technique that identifies the cause of a medical condition by eliminating the likely causes until the most probable cause is isolated.” *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1208 (8th Cir. 2000). The parties and their experts have identified multiple sources of and causes for turbulence and particulates in the operating theatre. *See, e.g.*, Def.’s Mot. for Reconsideration, MDL ECF No. 1719 at 13-15; Pls.’ Opp’n, MDL ECF No. 1786 at 13-17; Zimmerman Decl., Ex. 2, Samet Report, MDL ECF No. 1813 at 17 (indicating that “the Bair Hugger device is not a necessary cause, but a causal factor that increases risk of deep joint infection by adding an additional causal mechanism”). Plaintiffs have alleged

that the Bair Hugger is the probable cause or source of the infection in all cases before the Court in the MDL proceeding. But given all the possible causes of Plaintiffs' infections, what scientifically reliable process or methodology could Plaintiffs use to eliminate likely causes and identify the Bair Hugger as the most probable cause of infection and how does this process or methodology satisfy *Daubert*?

2. The Jeans (2018) study observed a significant decrease in the MSSA infection rate—predominately in the hip replacement group—after the introduction of the MSSA screening program. How do these findings, which suggest that MSSA screening confounded the McGovern Observational Study (2011), impact Dr. Samet's opinion that the Bair Hugger device constitutes a substantial contributing cause? What relevance do these findings have to the hip surgeries in this MDL proceeding? To the knee surgeries? How many cases in the MDL involve hip surgeries? How many involve knee surgeries?

3. Dr. Samet stated that “[t]he McGovern [Observational Study] supplies the only estimate of the risk associated for deep joint infection associated with the use of the forced-air warming Bair Hugger device.”<sup>1</sup> In light of this admission, if the Court finds that the Observational Study does not reliably support the allegations involving hip surgeries, what evidence could Plaintiffs rely on to establish that the Bair Hugger was the source of the infection?

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<sup>1</sup> “The McGovern paper supplies the only estimate of the risk associated for deep joint infection associated with use of the forced-air warming Bair Hugger device. So absent the quantitative estimate from that paper, it would be – while there would be a quite plausible mechanistic basis for increased risk, there would not been asked [sic] an association in – in the real world.” Hulse Decl., Ex. 9, Samet Dep., MDL ECF No. 1720 at 282:16-23.

Accordingly, IT IS ORDERED THAT:

1. The parties will address the issues described by the Court above. Both parties' responses will be due on May 16, 2019 by 5 PM.

Date: May 6, 2019

s/ Joan N. Ericksen  
JOAN N. ERICKSEN  
United States District Judge